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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/417,175 10/11/99 HARPER

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EXAMINER

GREGG C BENSON  
PFIZER INC  
EASTERN POINT ROAD  
GROTON CT 06340

OH, T

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

11/06/01

*9*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/417,175

Applicant(s)  
Harper et al

Examiner  
Oh Taylor Victor

Art Unit  
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 13, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 7-12, and 14-19 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-12, and 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 20) ☐ Other:

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Non-Final Rejection

1. Applicant's arguments with respect to claims 1, 7-12, and 14-19 have been considered but are moot in view of the new ground(s) of rejection.

**Election/Restriction**

The Examiner has decided to rejoin the groups I and II due to the failure to show the distinctness between the process of using and the product.

***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 7-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doogan et al (U.S. 4,962,128) in view of Howard et al (U.S. 5,597,826), and Pollinger et al (U.S. 6,136,347).

Doogan et al (U.S. 4,962,128) disclose a pharmaceutical composition containing sertraline hydrochloride (see col. 1, line 68) with a dose from 25 mg to 200 mg for treating anxiety-related disorders (see col. 2, lines 20-23); in addition, oral pharmaceutical formulations can be flavored by means of various agents ; the composition contains sertraline or its

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pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from col. 2 line 65 to col. 3, line 2).

However, Doogan et al differ from the instant invention in that 8 to 20 % ethanol is in glycerin, the flavoring agent is menthol, the preservative is butylhydroxytoluene, and each ml of the concentrate contains 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, and pharmacologically acceptable anions include methanesulfonate.

Howard et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61).

Furthermore, Pollinger et al (U.S. 6,136,347) discloses pharmaceutical preparations for masking unpleasant substances in liquid form, which can contain a protective substance such as butylhydroxytoluene for an excipient media (see col. 9, lines 37-38).

Concerning the claimed range of ethanol in glycerin, the reference is silent. However, Johnson teaches the use of diluents such as ethanol and glycerin; furthermore, Pollinger et al does point out that liquid auxiliaries such as ethanol, propylene glycol, polyethylene glycol (see col. 8, lines 58-60) can be employed in an amount of from .5 to 40 % (see col. 6, lines 54-56). Therefore, the person having an ordinary skill in the art had desired to use an optimum range of ethanol in

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glycerin, it would have been obvious for the skillful artisan in the art to have obtained the claimed range of ethanol in glycerin by a routine experimentation on the Johnson's ethanol and glycerin with Pollinger et al's parameter so as to form a proper liquid dose.

In reference to the flavoring agent being menthol, the reference is silent. However, Howard et al does teach that oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Furthermore, it is well-known in the art that menthol has been used for masking unpleasant flavors. Therefore, the skillful artisan in the art had desired to develop a unique menthol taste in the oral pharmaceutical composition containing sertraline hydrochloride, it would have been obvious for the skillful artisan in the art to have selected the menthol flavor as the masking agent for the product.

With respect to each ml of the concentrate contained 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, the references are silent. However, the pharmaceutical oral composition can contain various excipients with varied concentrations so as to meet special needs for the patients' use. Therefore, the composition of various known excipients do not have any patentable weight in the instant invention in the absence of unexpected results.

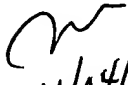
Therefore, if the skillful artisan in the art had desired to develop a unique oral pharmaceutical composition containing sertraline hydrochloride, claimed various excipients with a menthol flavor, it would have been obvious for the skillful artisan in the art to have used Johnson's diluents such as ethanol and glycerin and Pollinger et al's butylhydroxytoluene

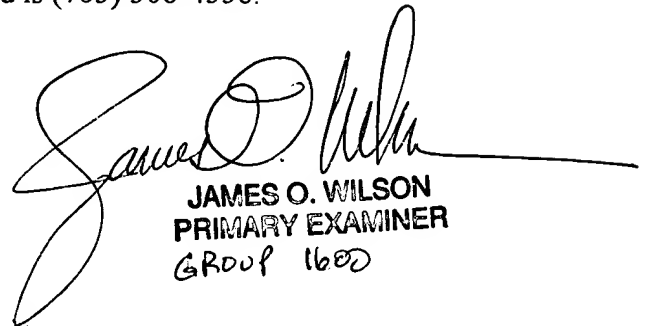
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preservative in Howard et al's oral pharmaceutical formulation so as to obtain an idealistic liquid product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

  
11/04/01

  
JAMES O. WILSON  
PRIMARY EXAMINER  
Group 1600